This message was sent to AIM, FAB, Health Systems, INE, IAP, LHD Health Officers, LHD Medical Directors, MACI, MACI 2, PH Imms Leads, COVID-19 Vaccine Providers, MCIR Regions, and Imms All Staff. I apologize for any duplication.

Dear Immunization Partners,

Emergency Use Instructions (EUI) for the COVID-19 vaccine have been amended since the initial EUI issuance on November 17, 2021 (initial guidance was provided in an email on November 19, 2021). **The Centers for Disease Control and Prevention (CDC) has issued the amended EUI for immediate distribution to COVID-19 vaccine recipients.**

What information should be provided to persons receiving a primary, additional, and/or booster dose of the COVID-19 vaccine by Pfizer-BioNTech or Moderna as described in the EUI?

- Provide the EUI Fact Sheet for Pfizer-BioNTech Recipients and Caregivers or EUI Fact Sheet for Moderna Recipients and Caregivers (please see below for additional information).
- Provide a CDC COVID-19 Vaccination Record Card to the recipient or their caregiver with the lot number, vaccine manufacturer, and date of administration recorded for primary, additional, and booster dose(s).
- Provide the v-safe information sheet to vaccine recipients/caregivers and encourage recipients to participate in v-safe. www.cdc.gov/vsafe.

The CDC has issued EUI for use of the COVID-19 vaccine by Pfizer-BioNTech and Moderna for primary, additional, and/or booster doses in certain individuals. The EUI are necessary because these uses extend beyond their FDA-approved labeling. The EUI and CDC's clinical guidance helps to ensure these individuals can get primary, additional, and/or booster doses of the COVID-19 vaccine by Pfizer-BioNTech or Moderna so they can be better protected against COVID-19.

The EUI are currently issued only for Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) COVID-19 vaccines since EUI can only apply to FDA-approved medical products. The COVID-19 vaccine by Pfizer-BioNTech and Moderna under EUI allow the same or similar uses seen below.

The CDC-issued EUI provides information on the following uses of the COVID-19 vaccine by Pfizer-BioNTech:

- A longer interval of 3-8 weeks between the first and second primary dose of Pfizer-BioNTech COVID-19 vaccine for persons 12 through 64 years, particularly for individuals at higher risk of mRNA COVID-19 vaccine-associated myocarditis (males 12 through 39 years) *.
- Primary doses(s) in those with certain immunocompromising conditions or those with incomplete primary dose series, and/or a booster dose for persons 12 years and older who received primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines.
- A 3-month interval for the booster dose after an mRNA vaccine primary series for persons 12 years and older who are moderately or severely immunocompromised.
- An additional dose in persons 18 years and older with certain immunocompromising conditions who received primary vaccination with the Janssen COVID-19 vaccine.

- Revaccination of moderately or severely immunocompromised persons 12 years and older who received certain therapies (i.e., hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy) and received dose(s) of COVID-19 vaccine prior to or during treatment.

The CDC-issued EUI provides information on the following uses of the COVID-19 vaccine by Moderna:

- A longer interval of 4-8 weeks between the first and second primary dose of Moderna COVID-19 vaccine for persons 18 through 64 years, particularly for individuals at higher risk of mRNA COVID-19 vaccine-associated myocarditis (males 12 through 39 years) *****.
- Primary dose(s) in those with certain immunocompromising conditions or those with incomplete primary dose series, and/or a booster dose for persons 18 years and older who received primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines
- A 3-month interval for the booster dose after an mRNA vaccine primary series for persons 18 years and older who are moderately or severely immunocompromised.
- An additional dose in persons 18 years and older with certain immunocompromising conditions who received primary vaccination with the Janssen COVID-19 Vaccine.
- Revaccination of moderately or severely immunocompromised persons 18 years and older who received certain therapies (i.e., hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)- T-cell therapy) and received dose(s) of COVID-19 vaccine prior to or during treatment.

***Providers should continue to recommend the 3-week (Pfizer-BioNTech) or 4-week (Moderna) interval for patients who:**

- Are at higher risk of having an inadequate response to the first mRNA vaccine dose
  - People who are moderately or severely immunocompromised
- Are at higher risk for severe COVID-19
- Need rapid protection, such as during high levels of community transmission
- Children ages 5-11 years

Refer to CDC's Interim Clinical Considerations for specific recommendations on the use of the COVID-19 vaccine allowed under the EUI. Relevant information is detailed in the sections titled: "People who received COVID-19 vaccine outside the United States", "People who received COVID-19 vaccine as part of a clinical trial", and "Recommendations for COVID-19 vaccination in moderately or severely immunocompromised people."

For frequently asked questions and answers about Emergency Use Instructions, please see: EUI-FAQ.pdf (cdc.gov)

If you have further questions, please contact checcimms@michigan.gov

Thank you for all your hard work to protect Michiganders from vaccine-preventable diseases!

The Immunization Nurse Education Team,
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